

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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21 CFR Part 520

**Oral Dosage Form New Animal Drugs; Sulfadimethoxine Tablets and Boluses;
Technical Amendment**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to codify an approved new animal drug application (NADA) held by Pfizer, Inc. The NADA provides for use of sulfadimethoxine (SDM) tablets to treat bacterial infections of dogs and cats.

EFFECTIVE DATE: (*Insert date of publication in the Federal Register.*)

FOR FURTHER INFORMATION CONTACT: Diane T. McRae, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pi., Rockville, MD 20855, 301-827-0212.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, is sponsor of NADA 15-102 that provides for oral use of SDM tablets for the treatment of SDM-susceptible bacterial infections of dogs and cats. The NADA was approved on December 14, 1964, for Hoffmann LaRoche, Inc. After several changes of sponsors, the current sponsor of the NADA, Pfizer, Inc., has filed a supplement to NADA 15-1 02 providing information supporting prior approval of their NADA and has requested codification. FDA concurs that NADA 15-1 02 was approved for use in dogs and cats on December 14, 1964, and therefore, amends 21 CFR 520.2220b to reflect the approval. Also, FDA is amending the regulation to add several editorial changes by removing paragraph (a), by redesignating paragraphs (b), (d), and (e) as paragraphs (a), (b), and (d), respectively, and by revising new paragraphs (a) and (d)(2) to reflect the codification.

Approval of this supplemental NADA does not require additional safety and effectiveness data. Therefore, a freedom of information summary is not required.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subject 21 CFR Part 520

Animal drugs.

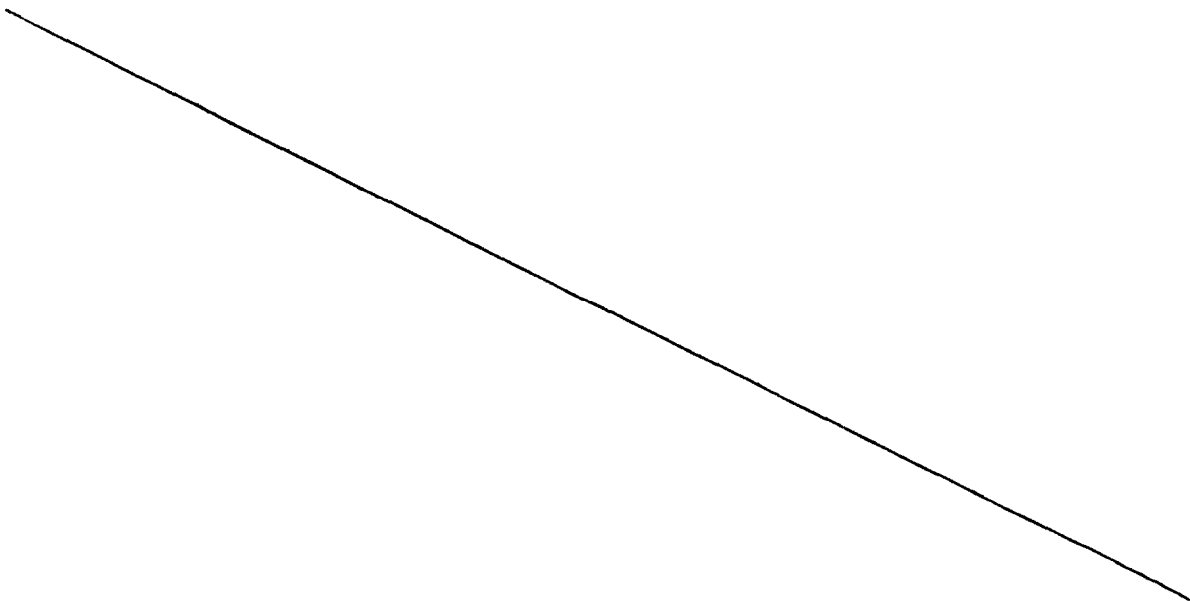
Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegate to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520-ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 520.2220b is amended by removing paragraph (a), by redesignating paragraphs (b), (d), and (e) as paragraphs (a), (b), and (d), respectively, and by revising newly redesignated paragraphs (a) and (d)(2) to read as follows:



§ 520.2220b Sulfadimethoxine tablets and boluses.

(a) *Sponsors.* Approval to firms identified in § 510.600(C) of this chapter as follows:

(1) To 000069, approval for use as in paragraphs (d)(1), (d)(2), and (d)(3) of this section.

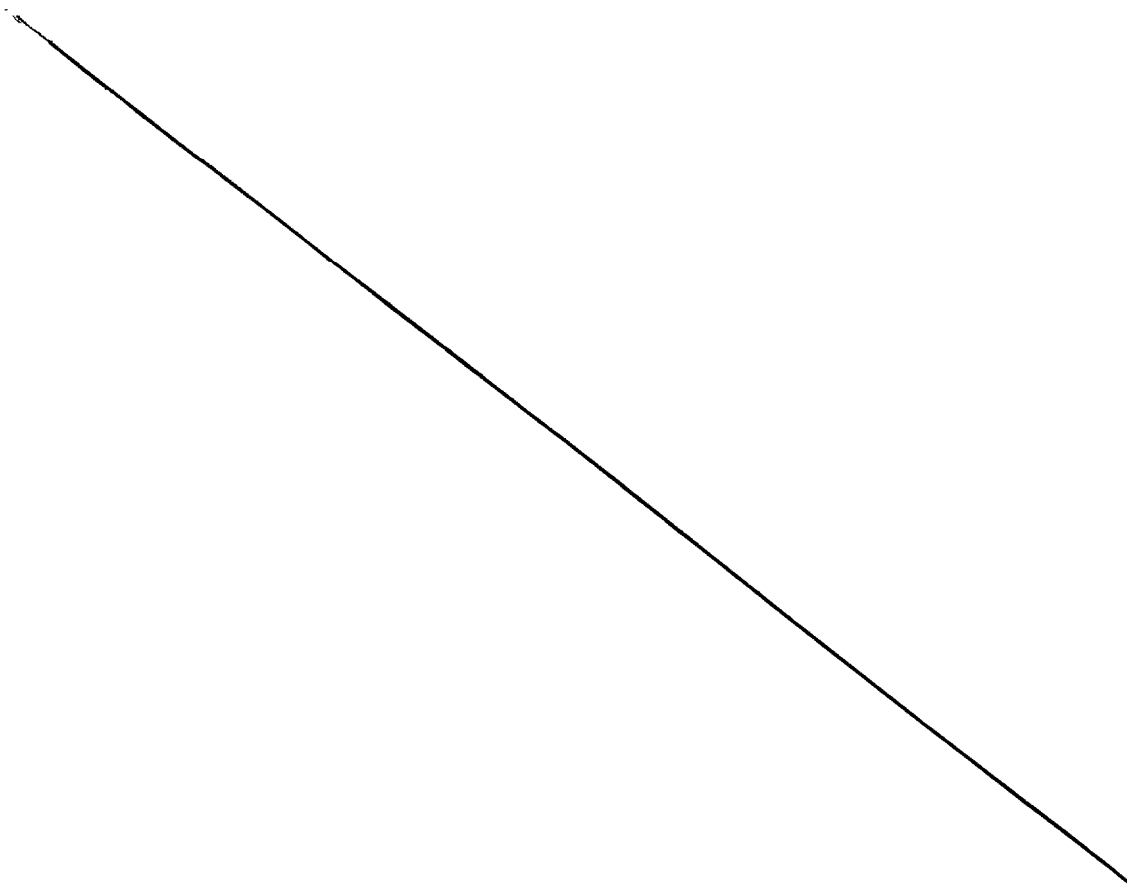
(2) To 000061, approval for use as in paragraph (d)(2) of this section.

* * * *

(d) * * *

(2) *Dogs and cats. (i) Amount.* 12.5 to 25 milligrams per pound of body weight.

(ii) *Indications for use.* Treatment of sulfadimethoxine-susceptible bacterial infections.



(iii) *Limitations.* Administer 25 milligrams per pound of body weight on the first day followed by 12.5 milligrams per pound of body weight per day until the animal is free of symptoms for 48 hours. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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Ann maso

Dated: March 17, 1999
March 17, 1999

Margaret Ann Miller

Margaret Ann Miller
Acting Director
Office of New Animal Drug
Evaluation
Center for Veterinary Medicine

[FR Dec. 99-???? Filed ??-??-99; 8:45 am]

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